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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,888	03/06/2002	Minoru Takebe	211A 3161 PCT	2747

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KODA & ANDROLIA

2029 Century Park East

Suite 1140

Los Angeles, CA 90067-2983

EXAMINER

LI, QIAN JANICE

ART UNIT

PAPER NUMBER

1633

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,888

Applicant(s)

TAKEBE ET AL.

Examiner

Q. Janice Li, M.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9-13 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9-13 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment submitted 6/12/06 has been entered. Claim 2 has been canceled. Claims 1, 3-7, 9-13, 15 have been amended. Claims 1, 3-7, 9-13, 15 are pending and under current examination.

Claim Objections

Claim 1 and 9 are objected to because of the following informalities: the phrase "after hematopoietic cell transplant radiation" should be amended to recite "following hematopoietic cell transplant after radiation", for example. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The prior rejection of Claims 1-7, 9-13, and 15 under 35 U.S.C. 112, first paragraph, is withdrawn in view of claim amendment.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The prior rejection of Claims 1-7, 9-13, and 15 under 35 U.S.C. 112, second paragraph, is withdrawn in view of claim amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The prior rejection of Claims 1-7, 9-13, and 15 under 35 U.S.C. 102(e) as being anticipated by *Takebe et al* (USP 6,303,161), is withdrawn in view of persuasive arguments and because the wt% of daizein as listed in tables 4 and 5 of the cited patent is much less than 70%, and the process of making the product differs in the step of the adding lactic acid bacteria.

Claims 1, 2-7, 9-13, and 15 stand rejected under 35 U.S.C. 102(e) as being anticipated by *Kelly et al* (USP 6,642,212).

Kelly et al teach a material comprising isoflavone aglycone (abstract), wherein the aqueous extract is further concentrated (column 12, line 57), wherein said

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isoflavone aglycone is comprised of 95% daidzein (genistein:daidzein=1:19, claim 13).

Thus, *Kelly et al* anticipate instant claims.

In the remarks, applicant first argues that in column 6, lines 6-8, *Kelly et al* points out certain ratios of genistein:daidzein as 1:2 or 2:1, wherein daidzein would be present in an amount from about 30-60%.

In response, it is noted the aforementioned ratio is one of the preferred embodiment of claimed invention by *Kelly et al* (see claim 5). However, it does not negate the other preferred embodiment where isoflavone aglycone is comprised of 95% daidzein with a ratio of genistein:daidzein=1:19 (claim 13).

Applicant then argues that claim 13 is an open-ended claim, does not limit the total amount of aglycones such as glycosides and glycitein present in the product, and only defines the ratio of genistein:daidzein.

In response, Applicant's attention is directed to the base claim 1 from which claim 13 depends, which reads "A HEALTH SUPPLEMENT COMPRISING A HEALTH SUPPLEMENTARY AMOUNT OF A NATURALLY OCCURRING PHYTO-OESTROGEN **SELECTED FROM ANY TWO OR MORE OF GENISTEIN, DAIDZEIN AND/OR THEIR GLYCOSIDES**". Thus, the claimed subject matter clearly encompasses the composition wherein isoflavone aglycone is consisting essentially of the genistein and daidzein, and the wt% of daidzein is at least 70%.

Applicant also argues, *Kelly et al* is directed to a health supplement while applicant's invention is now directed toward a material for promoting spleen colony formation after hematopoietic cell transplant post radiation.

In response, the intended use limitation bears little weight on the determination of novelty of the invention. In this case, the limitation “a material for promoting spleen colony formation...” does not carry patentable weight in the determination of anticipation for the claimed product. This is because a recitation of the intended use of the claimed invention must result in a structural difference between the claimed product and the prior art product in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Please also note with regard to those product-by-process claims presented that patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985).

The prior rejection of Claims 1-7, 9-13, and 15 under 35 U.S.C. 102(f), is withdrawn in view of persuasive argument responding to anticipation rejection by US patent 6,303,161.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Dave T. Nguyen** can be reached on 571-272-0731. The fax numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

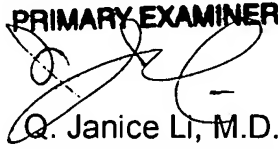
Any inquiry of formal matters can be directed to the patent analyst, **Victor Barlow**, whose telephone number is (571) 272-0506.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is **(866) 217-9197**. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

Q. JANICE LI, M.D.
PRIMARY EXAMINER

Q. Janice Li, M.D.
Primary Examiner
Art Unit 1633

QJL
August 10, 2006